

Attorney Docket No. 5470.269
Application Serial No.: 10/030,529
Filed: May 6, 2002
Page 2 of 11

IN THE SPECIFICATION

Please amend the substitute specification as follows.

On page 30, line 27 through page 31, line 16 of the substitute specification, please amend the bridging paragraph as follows.

The immunogens of the invention are immunogenic without adjuvant, however adjuvants may increase immunoprotective antibody titers or cell mediated immunity response. Such adjuvants could include, but are not limited to, Freund's complete adjuvant, Freund's incomplete adjuvant, aluminum hydroxide, aluminum phosphate, aluminum oxide or a composition that consists of a mineral oil, such as Marcol 52, or a vegetable oil and one or more emulsifying agents, dimethyldioctadecyl-ammonium bromide, ~~Adjuvax~~ ADJUVAX (Alpha-Beta Technology), Inject Alum (Pierce), Monophosphoryl Lipid A (Ribi Immunochem Research), MPL+ TDM (Ribi Immunochem Research), ~~Titermax~~ TITERMAX (CytRx), toxins, toxoids, glycoproteins, lipids, glycolipids, bacterial cell walls, subunits (bacterial or viral), carbohydrate moieties (mono-, di-, tri- tetra-, oligo- and polysaccharide) various liposome formulations or saponins. Other adjuvants that may be included in vaccine compositions of the present invention include, but are not limited to: surface active substances (e.g., hexadecylamine, octadecylamine, octadecyl amino acid esters, lysolecithin, dimethyl-dioctadecylammonium bromide), methoxyhexadecylglycerol, pluronic polyols; polyamines (e.g., pyran, dextran sulfate, poly IC, ~~carbopol~~ CARBOPOL); and peptides (e.g., muramyl dipeptide, dimethylglycine, tuftsin). The immunogen may also be incorporated into liposomes, or conjugated to polysaccharides and/or other polymers for use in a vaccine formulation. Combinations of various adjuvants may be used with the conjugate to prepare the immunogen formulation. Exact formulation of the vaccine compositions will depend on the particular conjugate, the species to be immunized and the route of administration.

On page 34, lines 6-25 of the substitute specification, please amend the paragraph as follows.

Attorney Docket No. 5470.269
 Application Serial No.: 10/030,529
 Filed: May 6, 2002
 Page 3 of 11

An inactivated virus or bacterial vaccine may be prepared. Inactivated vaccines are "dead" in the sense that their infectivity has been destroyed, usually by chemical treatment (e.g., formaldehyde treatment). Ideally, the infectivity of the virus or bacteria is destroyed without affecting the proteins which carry the immunogenicity of the vector. In order to prepare inactivated vaccines, large ~~quantities~~quantities of the recombinant vector expressing the desired epitopes are grown in culture to provide the necessary quantity of relevant antigens. A mixture of inactivated viruses or bacteria expressing different epitopes may be used for the formulation of "multivalent" vaccines. In certain instances, these "multivalent" inactivated vaccines may be preferable to live vaccine formulation because of potential difficulties arising from mutual interference of live viruses administered together. In either case, the inactivated virus or mixture of viruses should be formulated in a suitable adjuvant in order to enhance the immunological response to the antigens. Suitable adjuvants include: surface active substances, e.g., hexadecylamine, octadecyl amino acid esters, octadecylamine, lysolecithin, dimethyl-diocetadecylammonium bromide, N, N-dioctadecyl-N'-N'bis (2-hydroxyethyl-propane diamine), methoxyhexadecylglycerol, and pluronic polyols; polyamines, e.g., pyran, dextran sulfate, poly IC, ~~carbopol~~CARBOPOL; peptides, e.g., muramyl dipeptide, dimethylglycine, tuftsin; oil emulsions; and mineral gels, e.g., aluminum hydroxide, aluminum ~~phosphate~~phosphate, etc.

On page 38, line 30, through page 39, line 3, of the substitute specification, please amend the bridging paragraph as follows.

The antiserum to DsrA was produced as follows. Outer membranes from *H. ducreyi* strain 35000 were electrophoresed on large preparative well 12% SDS-PAGE gels. The gel was briefly stained and the corresponding 30 kDa band excised and electroeluted using a ~~Centrilutor~~CENTRILUTOR (Amicon) following the ~~manufacturers~~manufacturer's instructions. Mice were immunized a total of 3 times with 25 µg of gel purified protein per immunization. ~~Freunds~~Freund's complete adjuvant was used for the first immunization and incomplete for the remainder.